THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 17

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte THOMAS PALERMO

Appeal No. 2000-0448
Application No. 08/605,765

ON BRIEF

Before CALVERT, COHEN, and BAHR, Administrative Patent Judges.

CALVERT, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal from the final rejection of claims 1 to 28, all the claims remaining in the application.

The appealed claims are drawn to a method for enhancing occlusion, or for occluding, a body lumen, and are reproduced in the appendix of appellant’s brief.

The references applied in the final rejection are:

Guglielmi et al. (Guglielmi) 5,354,295 Oct. 11, 1994

Brunelle et al., Endovascular Electrocoagulation with a Bipolar Electrode and Alternating Current: A Follow-up Study in Dogs, 148 Radiology 413-415 (Aug. 1983) (Brunelle)

Claims 1 to 28 stand finally rejected as unpatentable over Guglielmi in view of Brunelle, under 35 U.S.C. § 103(a).

Rejection Pursuant to 37 CFR § 1.196(b)

Pursuant to 37 CFR § 1.196(b), claims 19 and 26 are rejected for failure to comply with 35 U.S.C. § 112, second paragraph.

Claim 19 reads:

> 19. The method of claim 18 wherein at least a portion of the surrounding wall is thermally damaged to induce local swelling and narrowing of the body lumen around the vaso-occlusive element and to temporarily lock the vaso-occlusive element in place at the target site, further comprising:
> releasing the vaso-occlusive element.

In view of the recitation that the vaso-occlusive element is temporarily locked in place by local swelling and narrowing of the body lumen, the recitation of "releasing" the element implies that it is released from the temporary lock. However, such a release of the element is contrary to appellant's

disclosure on page 6, lines 29 to 33, which states that the occlusion of the lumen (blood vessel) "will slowly and permanently lock the coil [element] in position at the occlusion site" (emphasis added),

while it is "temporarily held in place by the spasm or narrowing of the vessel." Thus, when claim 19 is read in light of the disclosure, this inconsistency between the claim and the disclosure renders the claim indefinite. Cf. In re Cohn, 438 F.2d 989, 993, 169 USPQ 95, 98 (CCPA 1971).

Claim 26 contains similar recitations and is indefinite for the same reason as claim 19.[1]

Rejection Under 35 U.S.C. § 103(a)

For the reasons stated above, we would have to engage in considerable speculation as to the meaning and scope of claims 19 and 26 in order to evaluate their rejection under § 103(a). Therefore, in accordance with In re Steele, 305 F.2d 859, 862, 134 USPQ 292, 295 (CCPA 1962), the rejection of claims 19 and 26 under § 103(a) will not be sustained, pro forma. This should not be taken as an indication, however, that these claims would necessarily be patentable over prior art if the § 112, second paragraph, rejection (supra) were overcome.

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[1]We speculate that appellant may have intended the step of "releasing" to mean releasing the vaso-occlusive element from some other apparatus (e.g., as disclosed at page 16, lines 32 to 34), but, unlike claim 22, no such apparatus is recited in claims 19 and 26.

Turning now to the remaining claims, the basis of the rejection under § 103(a) is set forth on pages 2 and 3 of the Examiner's Answer. In essence, the examiner finds that it would have been obvious, in view of Brunelle, to apply high frequency electrical energy instead of the DC voltage applied by Guglielmi.

First considering claim 1, appellant argues that it would not have been obvious to combine the references as proposed by the examiner because (1) neither reference discloses enhancing the occlusion of a partially occluded vessel, (2) neither reference discloses a vaso-occlusive element deployed at the target site before applying high frequency energy, and (3) neither reference discloses applying high frequency energy to and through a pre-deployed element to thermally damage the lumenal wall (brief, pages 9 and 10). Also appellant contends that Guglielmi teaches against applying energy which would cause injury to the vessel wall (brief, pages 14 and 15).

We do not agree with these arguments. As to argument (1), while the preamble of claim 1 does recite "A method of enhancing occlusion," the claim does not specify that the vessel is partially occluded. The argument is therefore not

commensurate with the scope of the claim. Argument (2) is likewise not well taken, because in the Guglielmi process, the electrical energy is not applied until after the coil has been deployed in place at the target site to be occluded (see col. 8, lines 14 to 18). Contrary to what appellant seems to believe, neither claim 1 nor claim 2 requires that the electrical energy be applied through a vaso-occlusive element (coil)[2] which was deployed at the target site at some time prior to deployment of the apparatus which applies the electrical energy.

Concerning appellant's remaining arguments, Brunelle, in the "Discussion" section on pages 414 and 415, states that there are several drawbacks to DC electrothrombosis, which is the method employed by Guglielmi to occlude, inter alia, an artery or vein (col. 6, line 59). Brunelle discloses that, as opposed to DC electrothrombosis:

> The main phenomenon in AC current electrocoagulation is local rise [in?] temperature leading to thermic coagulation of surrounding tissues . . . .

[2]We note that in claim 2, "coil" has no antecedent basis, and apparently should be --element--.

> This method has been [word obscured] surgical practice for many years and has greatly facilitated hemostasis. Thrombosis occurs secondary to direct trauma of the vessel wall; because of [the?] lesion of the vessel wall, the occlusion is permanent . . . . Because of the nature of the lesion, there is no risk of distal embolization. [pages 414 to 415]

Brunelle states in the "Conclusion" (page 415):

> Our results show that AC current electrocoagulation with a bipolar electrode is an effective way of occluding small vessels. It is a safe, reliable, and innocuous technique. In our experience, we have not seen distal embolization or vessel wall perforation. AC current electrocoagulation is faster than DC electrocoagulation, ...

We consider that this disclosure by Brunelle would suggest to one of ordinary skill in the art the use of high frequency (Brunelle discloses 100 KHz) AC current instead of DC in the electrothrombosis method of Guglielmi. The skilled worker would have been motivated to so modify the Guglielmi process by Brunelle's disclosure of the advantages of using AC, i.e., it is faster than DC, as well as being "a safe, reliable and innocous Technique." Appellant's argument that Guglielmi does not teach thermally damaging the lumenal wall is not

persuasive, because according to Brunelle, such damage is a characteristic of the use of AC current, as opposed to DC. Both AC and DC methods result in occlusion, and the fact that AC causes injury (trauma) of the vessel wall would not have dissuaded one of ordinary skill from using high frequency AC in place of Guglielmi's DC because Brunelle teaches not only that the use of AC "is a safe, reliable, and innocuous technique," but also "we have not seen distal embolization or vessel wall perforation" (supra).

We therefore conclude that claims 1 and 2 are unpatentable over Guglielmi in view of Brunelle, and will sustain the rejection of those claims as well as of claims 6 and 7, which appellant has not grouped or argued separately. 37 CFR § 1.192(c)(7).

Claim 3 reads:

> 3. The method of claim 1 wherein the applying step comprises:
> advancing an RF device through the lumen to the target site; and
> engaging at least one electrode on the RF device against the vaso-occlusive element which has already been deployed.

Appellant argues that this claim is patentable in that neither Guglielmi nor Brunelle discloses engaging an electrode against an already deployed vaso-occlusive element (coil). We agree with this argument, which has not been responded to by the examiner. Guglielmi positions the electrode and coil (e.g., 52 and 56) into position together as a single unit, and there is no teaching or suggestion in either reference that the electrode be advanced and engaged against an already-deployed coil, as claimed. Accordingly, the rejection of claim 3, and of claims 4 and 5 dependent thereon, will not be sustained. Likewise, since independent claim 10 contains similar limitations, we will not sustain its rejection, nor the rejection of claims 11 to 18 dependent thereon.

Claims 8 and 9 recite that the electrical resistance of the vaso-occlusive element is "substantially less than" (claim 8), or "substantially equal to or slightly less than" (claim

9)[3] the electrical resistance of tissue at the target site. Guglielmi does not expressly disclose this limitation, but, as pointed out by the examiner, does disclose that coil 28 or 56 is made of platinum (col. 7, line 57; col. 9, line 17), which is one of the materials of which appellant's coil may be made (page 13, line 28). It therefore appears that the coil of Guglielmi would inherently meet the limitations of these claims, appellant not having defined the scope of "substantially less" or "slightly less", and their rejection will be sustained.

Claim 20 reads:

> 20. A method for occluding a body lumen comprising:
> positioning at least one electrically conductive, vaso-occlusive element at a target site within the body lumen; and
> applying sufficient high frequency electrical energy to the vaso-occlusive element to generate a thermal reaction at the target site, while said electrically conductive, vaso-occlusive element remains in place at the target site and wherein the thermal reaction induces thrombosis to hold the element in place.

[3]The expression "substantially equal to" does not appear to have antecedent basis in the specification. 37 CFR § 1.75(d)(1).

We consider this claim to be unpatentable over Guglielmi in view of Brunelle, essentially for the reasons discussed above with respect to claim 1. Brunelle discloses, in the part of pages 414 and 415 quoted supra, that applying high frequency AC current will cause a local rise in temperature leading to thermic coagulation of surrounding tissues, and that there is trauma of the vessel wall. This would constitute a "thermal reaction at the target site," as claimed, and in practicing the method of Guglielmi as modified by Brunelle would inherently induce thrombosis to hold the element (coil) in place, for as appellant discloses at page 4, lines 18 to 33, such heating of the luminal wall induces fibrogenic occlusion of the vessel around the vaso-occlusive element, and at page 6, lines 29 to 31, the fibrogenic occlusion of the vessel "will slowly and permanently lock the coil in position at the occlusion site." Appellant’s argument that generating a thermal reaction would be contrary to Guglielmi’s disclosure of non-thermally detaching the coil is not persuasive, because the thermal reaction is in the vessel wall, not in the coil, which, being made of platinum, a low resistance material, would itself undergo little if any heating.

We will accordingly sustain the rejection of claim 20, as well as of dependent claims 21 to 25, which have not been argued separately.

The rejection of claim 27 will not be sustained, since the examiner has not identified, and we do not find, any suggestion or teaching in either reference of the particular step called for by this claim.

The rejection of claim 28 will be sustained. As noted above concerning claims 1 and 2, Guglielmi discloses initially deploying the coil at the target site, as claimed, before applying any electrical energy.

Conclusion

The examiner's decision to reject claims 1 to 28 under 35 U.S.C. § 103(a) is affirmed as to claims 1, 2, 6 to 9, 20 to 25 and 28, and reversed as to claims 3 to 5, 10 to 19, 26 and 27. Claim 19 and 26 are rejected pursuant to 37 CFR § 1.196(b).

In addition to affirming the examiner's rejection of one or more claims, this decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b) (amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)). 37 CFR § 1.196(b) provides, "[a] new ground of rejection shall not be considered final for purposes of judicial review."

Regarding any affirmed rejection, 37 CFR § 1.197(b) provides:

> (b) Appellant may file a single request for rehearing within two months from the date of the original decision . . . .

37 CFR § 1.196(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new

ground of rejection to avoid termination of proceedings (37 CFR § 1.197(c) as to the rejected claims:

> (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner . . . .
>
> (2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record . . . .

Should the appellant elect to prosecute further before the Primary Examiner pursuant to 37 CFR § 1.196(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If the appellant elects prosecution before the examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for reconsideration thereof.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART; 37 CFR § 1.196(b)

IAN A. CALVERT Administrative Patent Judge	)	
IRWIN CHARLES COHEN Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
JENNIFER D. BAHR Administrative Patent Judge	)	

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